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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,225	03/26/2001	Peter Hawkins	109068	5800

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,225	HAWKINS ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 4/19/06
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claim Status

The request for reconsideration filed on April 11, 2006 and an interview summary filed on April 21, 2006 have been acknowledged and entered.

Claims 9-13 are pending.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) in view of Rapoport (US 5,978,694) and further in view of Simpson (US 3,858,111).

Kritz teaches a method of detecting an analyte comprising the steps of providing a sample comprising a marker, a binder (recognition element), said marker having material comprising an externally, inductively detectable relative magnetic permeability constant of at least about 600, said recognition element binds to or competes for binding with the analyte, said marker and said recognition element induce in a transducer comprising a coil a first inductance value when said analyte is absent from said sample and a second inductance value when said analyte is present in said sample. The recognition element (binder) is immobilized to a matrix (substrate) – see

col. 6, lines 36-37. The sample containing the analyte and marker are added to the carrier. A competition or a sandwich reaction formed. The reaction was placed in a measuring coil and inductance changes noted. The inductance change in turn affected either the resonance frequency for an LC-circuit in which the coil was a part, or the balancing expressed as a voltage response, in a Maxwell Bridge in the coil was a part. The relationship between the change of resonance frequency in Hz, or the voltage difference in mV, is a linear relationship against the number of particles in the measuring solution, expressed as iron concentration. The molecular layer (recognition element) comprises an antibody/antigen and the second molecules are antigens or antibodies. (see col. 3, line 10-col. 4, lines 47; col. 5, line 10-col. 6, line 42; col. 9, lines 1-4).

However, Kritz does not teach measuring the difference in resonant frequency when the substrate is exposed to a magnetic field and when the substrate is not exposed to the magnetic field; a solenoid coil.

Rapoport teaches a method for detecting in a sample a substance that responds to an applied magnetic field, such as paramagnetic substance. The sample is placed in an applied magnetic field, and the effect of the sample on a performance characteristic of a first electrical conductor is measured by the first measuring means and the value is displayed and/or optionally inputted to a data storage and analysis means. Subsequent measurements of this same performance characteristic of the first electrical conductor are made over time, either continuously or at pre-determined intervals. The performance characteristics are inductance, capacitance, etc. (See col. 3, lines 35-37).

It is also desirable to compare the effect of the sample on the conductor in the presence of the applied magnetic field with the effect of the sample on the conductor in the absence of the applied magnetic field. (see col. 3, lines 20-26). Rapoport teaches a solenoid coil (figure 1).

It would have been obvious to one of ordinary skills in the art to measure the performance characteristic such as inductance of the sample in the presence and absence of the applied magnetic field as taught in Rapoport in the method of Kritz because that way the two measurements can be compared, taking into consideration the calibrations necessary to account for the differences, if any, in the performance characteristic of the first and second conductors. The corrected difference between the two measurements is then a function solely of the presence of a substance in the sample, which responds to the applied magnetic field.

However, Kritz and Rapoport fail to teach determining the different in resonance frequency of a tuned circuit which is connected to a phase locked loop comprising a driver which generates a driving signals for driving the tuned circuit, and a phase comparator for determining the phase difference between the driving signal and an output signal obtained from the tuned circuit, the difference in resonance frequency being determined by monitoring the performance of the phase locked loop.

Simpson teaches an apparatus for the measurement of absolute and relative concentration of chemical substances in processes wherein the nuclei of the substances being measured have defined magnetic moments. The apparatus in fig. 1 comprises a tuned circuit (13) comprising a driver (16) for driving signals for driving the

tuned circuit. The tuned circuit is connected to phase locked loop (which include the phase sensitive detector, the lock in detector, the RF oscillator) comprising a lock-in detector or phase comparator (26). The lock-in detector represents the difference in phase between the reference signal from oscillator 10 and signal from the tuned circuit 13. (see col. 4, line 24-col. 5, line 27). Simpson also teaches that the apparatus is used for concentration measurements of nuclei having magnetic moments in different types of processes. (see col. 9, lines 40-44).

It would have been obvious to one of ordinary skills in the art to use the apparatus of Simpson to measure the resonance frequency difference according to the method of Kritz and Rapoport because Simpson teaches that his apparatus is useful in measuring the concentrations of nuclei having magnetic moments in different types of processes and Kritz combined Rapoport teach a method of determining the concentration of chemical process of magnetic particles having magnetic moments. Tuned circuit is used to measure the resonance frequency or the signal induced by the magnetic field applied to the sample. Phase lock loop generates an error signal and compares the references signal with the signal produced by the tuned circuit thereby provides a final output signal indicative of the frequency difference.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) in view of Rapoport (US 5,978,694) further in view of Simpson as applied to claim 9 above further in view of Houghton et al. (US 5,679,342).

Kritz and Rapoport and Simpson have been discussed above.

However, Kritz and Rapoport and Simpson fail to teach a plastic strip as the substrate.

Houghton et al. teaches an assay wherein the receptor layer is immobilized on a matrix/solid support such as plastic strips, microliter plates, or any surface onto which antigen may be immobilized.(See col. 19, lines 45-51).

It would have been obvious to one of ordinary skills in the art that using matrix/solid support such as plastic strips is well known in the art. Thus, one of ordinary skills in the art would find it obvious to use plastic strips as taught by Houghton in the modified method of Kritz and Rapoport and Simpson since Kritz suggested that the receptors are immobilized to a matrix and it is well known in the art that matrix for immobilizing receptor can be plastic strips for these plastic strips are polymers with compatible functional groups that immobilize the receptors securely on the strips and do not interfere with the molecular interaction of the receptor and the target analyte.

Response to Arguments

Applicant's arguments filed April 11 and 21, 2006 have been fully considered but they are not persuasive.

Applicant argues that Simpson does not teach a circuitry that can be considered to correspond to the circuitry that is the subject matter of the pending claims. The phase sensitive detector in Simpson is used to facilitate measurement of in-phase and quadrature signals at resonance. A phase difference between the reference signal and any return signal can be changed by adjusting the phase shifter, but there is no

feedback loop at all present in the device disclosed in Simpson that corresponds to a phase-locked loop.

During the personal interview on April 19, 2006, Applicant was advised that since Simpson teaches a tuned circuit connected to a phase locked loop (which include the phase sensitive detector, the lock-in detector, the RF oscillator) comprising a lock-in detector or phase comparator (26). The lock-in detector represents the difference in phase between the reference signal from oscillator 10 and signal from the tuned circuit 13 (see col. 4, line 24-col. 5, line 27), Simpson satisfies the requirement of the present claims especially the definition of a phase-locked loop because the claims as now recite define the phase locked loop as comprising a phase comparator and a driver.

Applicant continues to traverse this rejection in the response filed on April 21, 2006, by submitting that simply finding a driver and a phase comparator in the Simpson reference does not render obvious the feature of the phase-locked loop.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., other components or features of the phase-locked loop beside comprising a driver and a phase comparator) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims as now recite define the phase locked loop as comprising a driver for generating a driving signal for driving the turned circuit, and a phase comparator for determining the phase difference between the driving signal and an output signal

obtained from the tuned circuit and nothing else. If Simpson has all the claimed features of the phase-locked loop, then Simpson would be a sufficient prior art for those claimed features.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
August 17, 2006

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SUPERVISORY PATENT EXAMINER
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